



05-28-04

IFW

Attorney's Docket No.: 17181-002005 / 24739-2101G

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bruce A. Lessey, et al. Art Unit : 1644
Serial No. : 10/762,441 Examiner : Unknown
Filed : January 21, 2004 Conf. No. : 5177
Conf. No. : 20985
Title : DETERMINATION OF ENDOMETRIAL RECEPTIVITY TOWARD
EMBRYO IMPLANTATION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are Enclosures that were inadvertently omitted from the Preliminary Amendment mailed May 14, 2004, and a return postcard. The Enclosures are copies of the 1) filing receipt for the above-captioned application; 2) cover page of U.S. Patent No. 5,279,941; and 3) cover page of U.S. Patent application No. 2003/0228636.

☒ The Commissioner is hereby authorized to charge any fee, including any submitted herewith if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

Attorney Docket No. 17181-002005
Address all correspondence to:
Stephanie L. Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-4777
Facsimile: (202) 626-7796
email: seidman@fr.com

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

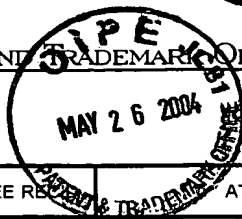
"Express Mail" Mailing Label Number EV 471528595 US
Date of Deposit May 26, 2004

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie L. Seidman

COPY

UNITED STATES PATENT AND TRADEMARK OFFICE



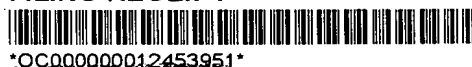
UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE RE	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/762,441	01/21/2004	1644	385	24739-2101G	7	16	1

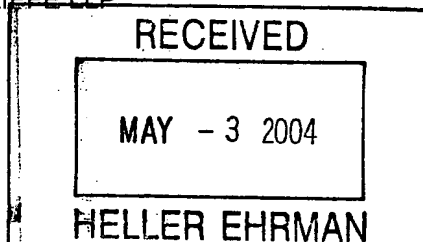
CONFIRMATION NO. 5177

Stephanie Seidman
 HELLER EHRMAN WHITE & McAULIFFE LLP
 7th Floor
 4350 La Jolla Village Drive
 San Diego, CA 92122

FILING RECEIPT



OC000000012453951



Date Mailed: 04/28/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Bruce Lessey, Hillsborough, NC;

RECEIVED

MAY 03 2004

FISH & RICHARDSON, P.C.
SAN DIEGO

Domestic Priority data as claimed by applicant

This application is a DIV of 10/463,130 06/16/2003
 which is a CON of 09/149,183 09/08/1998 PAT 6,733,979
 which is a CON of 08/756,211 11/25/1996 ABN
 which is a DIV of 08/400,270 03/03/1995 PAT 5,578,306
 which is a CON of 08/126,063 11/01/1993 ABN
 which is a DIV of 07/897,706 06/12/1992 PAT 5,279,941

Foreign Applications

If Required, Foreign Filing License Granted: 04/26/2004

Projected Publication Date: 08/05/2004

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

DOCKETED

Title

Determination of endometrial receptivity toward embryo implantation

Preliminary Class

435



**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



US005279941A

United States Patent [19]

Lessey

[11] Patent Number: 5,279,941

[45] Date of Patent: Jan. 18, 1994

[54] DETERMINATION OF ENDOMETRIAL RECEPTIVITY TOWARD EMBRYO IMPLANTATION

[75] Inventor: Bruce Lessey, Havertown, Pa.

[73] Assignee: Trustees of the University of Pennsylvania, Philadelphia, Pa.

[21] Appl. No.: 897,706

[22] Filed: Jun. 12, 1992

[51] Int. Cl.⁵ G01N 33/554; G01N 33/577

[52] U.S. Cl. 435/7.21; 435/960; 436/510; 436/519; 436/65

[58] Field of Search 435/7.21, 810, 960; 436/510, 519, 548, 65, 814; 530/388.25, 389.3, 391.3

[56] References Cited

U.S. PATENT DOCUMENTS

5,057,604 10/1991 Brown 530/387

OTHER PUBLICATIONS

Lessey et al "Integrin Adhesion Molecules in the Human Endometrium" J. Clin. Invest. 90:188-195 Jul. 1992.

Lessey et al, abstract #401 from 38th Annual Meeting of the Society for Gynecologic Investigation Mar. 1991.

Lessey et al, abstract from 2nd International Conference on the Extracellular Matrix of the Reproductive Tract May 1992.

Vanderpuye et al "A vitronectin-receptor-related molecule in human placental brush border membranes" Biochem J 280:9-17 Nov. 1991.

Tabibzadeh "Patterns of expression of integrin molecules in human endometrium throughout the menstrual cycle" Human Reproduction 7(6):876 1992.

Getzenberg et al., "The Tissue Matrix: Cell Dynamics and Hormone Action", *Endocrine Rev.*, 11:399-417 (1990).Albelda et al., "Integrins and Other Cell Adhesion Molecules", *FESEB J.*, 4:2868-2880 (1990).

Buck et al., "Integrin, a Transmembrane Glycoprotein Complex Mediating Cell-Substratum Adhesion", J. Cell Sci. Suppl., 8:231-250 (1987).

Burridge et al., "Focal Adhesions: Transmembrane

Junctions Between the Extracellular Matrix and the Cytoskeleton", *Ann. Rev. Cell. Biol.* 4: 487-525 (1988). Hemler, M. E. "VLA Proteins in the Integrin Family: Structures, Functions and Their Role on Leukocytes", *Annu. Rev. Immunol.* 8:365-400 (1990).Rogers and Murphy, "Uterine Receptivity for Implantation: Human Studies", in *Blastocyst Implantation*, Yoshinaga, K. ed., Sero Symposia, pp. 231-238 (1989). Satyaswaroop et al., "Isolation and Culture of Human Endometrial Glands", *J. Clin. Endocr. Metab.*, 48:639-641 (1979).Bennett et al., "Inhibition of Fibrinogen Binding to Stimulated Human Platelets by a Monoclonal Antibody" *PNAS*, vol. 80, 2417-2421 (1983).Kohler and Milstein, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity" *Nature*, 256: 495-497 (1975).Noyes et al., "Dating the Endometrial Biopsy", *Fertil. & Steril.*, 1:3-25 (1950).Lowry et al., "Protein Measurement with Folin Phenol Reagent", *J. Biol. Chem.*, 193:265-275 (1951).

(List continued on next page.)

Primary Examiner—Esther L. Kepplinger

Assistant Examiner—Nancy J. Parsons

Attorney, Agent, or Firm—Woodcock Washburn Kurtz, Mackiewicz & Norris

[57]

ABSTRACT

Methods are provided for detecting receptivity of mammalian endometrium to embryo implantation comprising obtaining a sample of the endometrium, contacting the endometrium with a monoclonal antibody for β_3 integrin and detecting β_3 integrin in the endometrium. The invention also provides for methods of diagnosing infertility in a mammal and methods of detecting the window of embryo implantation in endometrium. Methods of in vitro fertilization, methods of preventing embryo implantation and a method of monitoring endometrial maturation are also within the scope of the present invention. The present invention is also directed to contraceptives. Diagnostic kits useful in the practice of the methods of the invention are also provided.

32 Claims, 6 Drawing Sheets



- (19) **United States**
(12) **Patent Application Publication**
Lessey
- (10) **Pub. No.: US 2003/0228636 A1**
(43) **Pub. Date: Dec. 11, 2003**

- (54) **DETERMINATION OF ENDOMETRIAL
RECEPTIVITY TOWARD EMBRYO
IMPLANTATION**

063, filed on Nov. 1, 1993, now abandoned, which is a division of application No. 07/897,706, filed on Jun. 12, 1992, now Pat. No. 5,279,941.

- (76) Inventor: **Bruce Lessey, Hillsborough, NC (US)**

Publication Classification

Correspondence Address:
Stephanie Seldman
Heller Ehrman White & McAuliffe LLP
7th Floor
4350 La Jolla Village Dr.
La Jolla, CA 92122 (US)

- (51) **Int. Cl.⁷** **G01N 33/53; G01N 33/567**
(52) **U.S. Cl.** **435/7.2**

- (21) Appl. No.: **10/463,130**
(22) Filed: **Jun. 16, 2003**

(57) **ABSTRACT**

Related U.S. Application Data

- (60) Continuation of application No. 09/149,183, filed on Sep. 8, 1998, which is a continuation of application No. 08/756,211, filed on Nov. 25, 1996, now abandoned, which is a division of application No. 08/400,270, filed on Mar. 3, 1995, now Pat. No. 5,578,306, which is a continuation of application No. 08/126,

Methods for detecting receptivity of mammalian endometrium to embryo implantation comprising obtaining a sample of the endometrium, contacting the endometrium with a monoclonal antibody for β_3 and detecting β_3 in the endometrium. The invention also provides for methods of diagnosing infertility in a mammal and methods of detecting the window of embryo implantation in endometrium. Methods of in vitro fertilization, methods of preventing embryo implantation and a method of monitoring endometrial maturation are also within the scope of the present invention. The present invention is also directed to contraceptives. Diagnostic kits useful in the practice of the methods of the invention are also provided.